



**FOR US POSTAL SERVICE DELIVERY:**

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July 13, 2000

Joseph J. Ferretti, Ph.D.  
Senior Vice President and Provost  
University of Oklahoma Health Sciences Center  
Robert M. Bird Library Building, Room 221  
1000 Stanton L. Young Boulevard  
Oklahoma City, Oklahoma 73104

**RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1448**

Dear Dr. Ferretti:

The Office for Human Research Protections (OHRP) has reviewed your July 10, 2000 report which included (i) the findings of UOHSC's investigation into the allegations of noncompliance with the Department of Health and Human Services (HHS) regulations for the protection of human subjects that were cited in my letter of June 12, 2000; (ii) the proposed revised University of Oklahoma Health Sciences Center (UOHSC) MPA document; (iii) a detailed description of corrective actions already taken by the UOHSC, as well as detailed corrective action plans for the near future; and (iv) a detailed description of the UOHSC's planned programs for ensuring that all IRB members, all IRB staff, and all investigators are educated, on an on-going basis, about the ethical principles and regulatory requirements for the protection of human subjects.

**OHRP Findings**

Based its review of your report, OHRP finds that the UOHSC has developed satisfactory corrective action plans that address all of the concerns and deficiencies documented in OHRP's letter of June 29, 2000. Furthermore, OHRP finds that the UOHSC has completed each required action stipulated in that letter.

**OHRP Actions**

(1) In view of the above determinations, OHRP hereby approves the revision of the University of Oklahoma Health Sciences Center Human Subjects Assurance (MPA M-1448) and reinstates MPA M-1448 with respect to the UOHSC-Tulsa. This reinstatement, effective immediately, provides the Assurance required by Department of Health and Human Services regulations at 45 CFR 46.103(a) for Federally supported research involving human subjects at the UOHSC-Tulsa. The MPA will retain its previous expiration date of November 7, 2004. A copy of the approved revised MPA document is enclosed for your records.

The IRBs designated under the approved UOHSC MPA have been assigned the identification numbers 01XB, 02, and 03XB. These IRB numbers, along with your Assurance number (M-1448), will be required on certain forms (e.g., PHS-398, PHS-2590) and other correspondence.

An XB suffix indicates that the IRB has no (or an insufficient number of) members expert in the behavioral sciences. A proposed activity requiring behavioral expertise for assessing risks, benefits, and adequacy of safeguards cannot be certified under an XB restriction. The XB restriction for IRB-01 and IRB-03 can be removed at any time if a revised roster with appropriate additional members (e.g., psychiatrists, psychologists, or sociologists) is submitted to OHRP for approval.

(2) The UOHSC MPA is hereby restricted according to the following conditions and required actions:

(a) All Federally supported research projects at UOHSC-Tulsa involving human subjects are to remain suspended in accordance with OHRP's letter of June 29, 2000, until one of the IRBs designated under the revised MPA reviews and approves the research. Certification of such IRB approval must be submitted in writing to the appropriate official(s) at the supporting Federal department or agency prior to resumption of the research.

(b) In its June 29, 2000 letter, OHRP expressed concern that some research involving human subjects at the UOHSC-Tulsa was inappropriately designated as being exempt from the requirements of HHS regulations at 45 CFR Part 46. The UOHSC must inventory all active exempt human subject research being conducted at the UOHSC-Tulsa and ensure that such research satisfies the criteria for exemption under HHS regulations at 45 CFR 46.101(b).

(c) OHRP hereby removes from coverage under the MPA any Federally supported research conducted by Dr. Michael McGee. For any HHS-supported award to UOHSC involving human subjects research for which Dr. McGee is a principal investigator or co-investigator, the UOHSC must submit to OHRP a Single Project Assurance for review and approval prior to the initiation of any research activities involving human subjects supported by the award.

For any human subjects research being conducted by Dr. McGee and supported by another Federal Department or Agency, the UOHSC should consult with appropriate officials at that Department or Agency regarding implementation of an appropriate Assurance mechanism.

(d) By August 31, 2000, the UOHSC must submit to OHRP a follow-up report regarding its investigation into the serious noncompliance with HHS regulations for the protection of human subjects involving (i) the melanoma vaccine research conducted by Dr. McGee; (ii) the actions of the now disbanded UOHSC-Tulsa IRB (in particular the Chair, Dr. Daniel Plunkett); and (iii) the actions of other senior officials at the UOHSC-Tulsa following the delivery of the March 16, 2000 audit report from Hausmann & Wynne Associates, Inc., to officials at the UOHSC-Tulsa. Your report should describe any additional actions taken by the institution in response to the identified noncompliance.

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(e) By October 15, 2000, the UOHSC must submit to OHRP a progress report regarding implementation of its corrective action plans. This progress report should include the following:

- (i) A summary of the progress made in implementing the planned educational programs for all IRB members, all IRB staff, and all research investigators about the ethical principles and regulatory requirements for the protection of human subjects.
- (ii) A summary of the IRBs progress in reviewing all research at the UOHSC-Tulsa involving human subjects.
- (iii) The minutes of all IRB meetings convened in September 2000.
- (iv) Any revised written IRB policies and procedures.

OHRP appreciates the commitment of the UOHSC to the protection of human subjects. Do not hesitate to contact me should you have any questions.

Sincerely,



Michael A. Carome, M.D.  
Chief, Compliance Oversight Branch  
Division of Human Subject Protections

Enclosure

cc: Senator David Boren, President, Oklahoma University  
Ms. Nancy Nisbett, Director, Office of Research Administration, UOHSC  
Ms. Elizabeth H. Cothran, Research Project Coordinator, IRB, UOHSC  
Dr. Ken Lackey, President, UOHSC-Tulsa  
Dr. Harold L. Brooks, Dean, UOHSC-Tulsa  
Dr. Joan Walker, Chair, IRB-01 and -03, UOHSC  
Dr. Karen Beckman, Chair, IRB-02, UOHSC  
Dr. Michael McGee, Surgery Department, UOHSC-Tulsa  
Dr. John Mather, Department of Veterans Affairs  
Commissioner, FDA  
Dr. David Lepay, FDA  
Dr. James F. McCormack, FDA  
Mr. Joseph Salewski, FDA  
Dr. Melody H. Lin, OHRP  
Dr. J. Thomas Puglisi, OHRP  
Ms. Michele Russell-Einhorn, OHRP  
Dr. Clifford C. Scharke, OHRP  
Dr. Katherine Duncan, OHRP  
Ms. Carolyn Hudley, OHRP